

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claims 1 – 135 (Cancelled).

136. (New) A method of treating a subject in need comprising administering to the subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of fenofibrate or a salt thereof having an effective average particle size of less than about 2000 nm;
- (b) there is no substantial difference between the AUC of the composition when administered to a human subject under fed as compared to fasted conditions; and
- (c) there is no substantial difference between the  $C_{\max}$  of the composition when administered to a human subject under fed as compared to fasted conditions.

137. (New) The method of claim 136, wherein administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state.

138. (New) The method of claim 137, wherein bioequivalency of the composition is established by:

- (a) a 90% Confidence Interval for AUC which is between 0.80 and 1.25;  
and
- (b) a 90% Confidence Interval for  $C_{\max}$ , which is between 0.80 and 1.25.

139. (New) The method of claim 137, wherein bioequivalency of the composition is established by:

- (a) a 90% Confidence Interval for AUC which is between 0.80 and 1.25;  
and
- (b) a 90% Confidence Interval for  $C_{\max}$  which is between 0.70 and 1.43.

140. (New) The method of claim 136, wherein the composition is bioequivalent to a micronized TRICOR® 54 mg fenofibrate oral solid dosage form.

141. (New) The method of claim 136, wherein the composition is bioequivalent to a micronized TRICOR® 160 mg fenofibrate oral solid dosage form.

142. (New) The method of claim 141, wherein the composition is a single daily dose.

143. (New) The method of claim 136, wherein the composition is bioequivalent to a micronized TRICOR® 200 mg fenofibrate oral solid dosage form.

144. (New) The method of claim 143, wherein the composition is a single daily dose.

145. (New) The method of claim 136, wherein the difference in AUC of the fenofibrate composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than about 35%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.

146. (New) The method of claim 136, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139  $\mu\text{g/mL.h}$ .

147. (New) The method of claim 136, wherein the composition exhibits a  $T_{\text{max}}$  after administration to fasting human subjects selected from the group consisting of less than about 6 hours, less than about 5 hours, less than about 4 hours, less than about 3 hours, less than about 2 hours, less than about 1 hour, and less than about 30 minutes.

148. (New) The method of claim 136, wherein in comparative pharmacokinetic testing with a TRICOR<sup>®</sup> 160 mg tablet or 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate, the composition exhibits a  $T_{\text{max}}$  selected from the group consisting of less than about 90%, less than about 80%, less than about 70%, less than about 50%, less than about 30%, and less than about 25% of the  $T_{\text{max}}$  exhibited by the TRICOR<sup>®</sup> tablet or capsule.

149. (New) The method of claim 136, wherein the fenofibrate or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg fenofibrate or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg fenofibrate or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg fenofibrate or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg fenofibrate or a salt thereof per kg of composition.

150. (New) The method of claim 136, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a TRICOR<sup>®</sup> 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC or a 90% Confidence Interval of between 0.80 and 1.25 for AUC and a 90% Confidence Interval of between 0.70 to 1.43 for  $C_{\max}$ .

151. (New) The method of claim 136, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and

(b) the composition is bioequivalent to a TRICOR<sup>®</sup> 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{\max}$  and AUC or a 90% Confidence Interval of between 0.80 and 1.25 for AUC and a 90% Confidence Interval of between 0.70 to 1.43 for  $C_{\max}$ .

152. (New) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

153. (New) The method of claim 152, wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

154. (New) The method of claim 152, wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

155. (New) The method of claim 152, wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

156. (New) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

157. (New) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

158. (New) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

159. (New) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

160. (New) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

161. (New) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

162. (New) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

163. (New) The method of claim 136, wherein the fenofibrate or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

164. (New) The method of claim 136, wherein the effective average particle size of the particles of fenofibrate or a salt thereof are selected from the group consisting of less than

about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

165. (New) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a  $D_{99}$  of less than about 500 nm.

166. (New) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a  $D_{50}$  of less than about 350 nm.

167. (New) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a mean particle size of less than about 100 nm.

168. (New) The method of claim 136, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.



169. (New) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

170. (New) The method of claim 169, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

171. (New) The method of claim 170, wherein the composition is formulated into a tablet dosage form.

172. (New) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

173. (New) The method of claim 136, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

174. (New) The method of claim 136, wherein within about 5 minutes at least about 20%, at least about 30%, or at least about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

175. (New) The method of claim 136, wherein within about 10 minutes at least about 40%, at least about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

176. (New) The method of claim 136, wherein within about 20 minutes at least about 70%, at least about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

177. (New) The method of claim 136, wherein:

- (a) within about 5 minutes at least about 30% of the composition is dissolved;
- (b) within about 10 minutes at least about 70% of the composition is dissolved; and
- (c) within about 20 minutes at least about 90% of the composition is

dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

178. (New) The method of claim 136, wherein:

(a) within about 5 minutes at least about 40% of the composition is dissolved;

(b) within about 10 minutes at least about 80% of the composition is dissolved; and

(c) within about 20 minutes at least about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

179. (New) The method of claim 136, wherein upon administration, the composition redisperses such that the redispersed particles of fenofibrate or a salt thereof have an effective average particle size of less than about 2 microns.

180. (New) The method of claim 179, wherein the redispersed particles of fenofibrate or a salt thereof have an effective average particle size selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than

about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

181. (New) The method of claim 136, wherein the composition redisperses in a biorelevant media such that the redispersed particles of fenofibrate or a salt thereof have an effective average particle size of less than about 2 microns.

182. (New) The method of claim 181, wherein the redispersed particles of fenofibrate or a salt thereof have an effective average particle size selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

183. (New) The method of claim 136, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

184. (New) The method of claim 136, wherein the subject is a human.

185. (New) The method of claim 136, wherein the method is used to treat a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, and peripheral vascular disease .

186. (New) The method of claim 136, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

187. (New) The method of claim 136, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

188. (New) The method of claim 136, wherein the method is used to decrease the risk of pancreatitis.

189. (New) The method of claim 136, wherein the method is used to treat indications where lipid regulating agents are typically used.